REMARKS

Status of the claims

Claims 57, 63, 64, 66, 68-71 and 87-102 were pending and claims 57, 63, 64, 66, 68-71 and 87-90 were under active consideration.

By amendment herein, claim 57 has been amended to incorporate the limitations of previous claims 64 and 66 and to indicate that the zinc finger protein binds to a target site in an accessible region of chromosomal cellular chromatin. See, e.g., page 10, lines 7-10; and pages 13-15. Withdrawn claim 91 has been amended to depend from claim 57 and withdrawn claims 93 and 96 have been amended to properly depend from claim 91. Accordingly, claims 63, 64, 66, 87-90 and withdrawn claims 92, 94 and 95 have been canceled, without prejudice or disclaimer. Dependent claims 68-71 have been amended to depend from claim 57 rather than canceled claim 66.

Thus, claims 57, 68-71, 87-91, 93 and 96-102 are pending as shown above and claims 57, 66, 68-71 and 87-90 are under active examination. Inasmuch as withdrawn claims 91, 93, and 96-102 have been amended to contain all of the limitations of the elected composition claims, they are eligible for rejoinder upon allowance of the claims under consideration.

Rejections Withdrawn

Applicants note with appreciation withdrawal of all previous rejections.

Claim Interpretation

On pages 3 to 5 of the Office Action, the Examiner indicated that claim 57 was understood to encompass:

> (i) a non-naturally occurring molecule (having only a synthetic structure), bound to a DNA which, in the context of its natural DNA or plasmid in which it existed in a cell under some specific condition and time of development, would have also contained chromatin structural elements;
>
> (ii) a cell comprising a non-naturally occurring molecule (having only synthetic structure), bound to a DNA which comprises chromatin structural elements.

Applicants appreciate the Examiner's clarification of his interpretation as compared to the previous Examiner's. In light of the foregoing amendments, however, Applicants note that the claims encompass cells containing a complex between any non-naturally occurring zinc finger protein and chromosomal cellular chromatin. As noted above, a non-naturally occurring zinc finger protein is any protein that is not found in nature and, therefore includes both synthetic proteins and naturally occurring sequences in a non-naturally occurring context (*e.g.*, a single naturally occurring zinc finger in the context of one or more additional non-naturally occurring zinc fingers). Furthermore, the "chromosomal cellular chromatin" component of the claimed complex includes only cellular chromatin in its native context and excludes reconstituted chromatin or plasmid DNA.

Claim Objections

Claim 57 was objected to on the grounds that the recitation "the binding site comprises a target site" was alleged to be duplicative and confusing and on the grounds that the recitation "is sensitive to a probe of chromatin structure" was confusing. (Office Action, page 5). In addition, it was noted that previous claims 87-90 would be objected to under 37 C.F.R. § 1.75 as duplicative of claim 57. (Office Action, pages 16-17).

The foregoing amendments to claim 57 and the cancellation of claims 87-90 without prejudice or disclaimer obviate the objections.

Obviousness-type double patenting

The examined claims were various rejected under the judicially created doctrine of obviousness-type double patenting over 30 different U.S. Patents. (Office Action, pages 6-16).

All but two of the cited patents include only method claims. The Patent Office routinely imposes a Restriction Requirement as between as between compositions and methods of making or using these compositions, indicating composition and method claims are considered to be patentably distinct. Indeed, such a Restriction was imposed in the instant case. Inasmuch as obviousness-type double patenting rejections are

improper when the subject matter of the conflicting claims has been determined to be distinct, the rejection should be withdrawn. See, also, MPEP § 804.01.

Furthermore, with regard to the two patents that have composition claims (U.S. Patent Nos. 7,163,824 and 7,026,462), Applicants note that an obviousness-type double patenting rejection requires a showing that the claims at issue are obvious over the conflicting claims. In the instant case, this would require showing that claims drawn to a complex between a zinc finger protein and a target site in an accessible region of cellular chromatin are obvious over claims drawn to a cell comprising at least two zinc finger nucleases (U.S. Patent No. 7,163,824) or claims drawn to polynucleotides encoding specific zinc finger proteins (U.S. Patent No. 7,026,462).

As detailed below, the evidence of record establishes that zinc finger proteins as described in U.S. Patent Nos. 7,163,824 and 7,026,462 were known to be functional when bound to non-accessible, i.e., when a complex between a non-naturally occurring zinc finger protein and a non-accessible region of cellular chromatin. See, page 5 and Appendix A (Zhang et al.) of Response filed December 22, 2005 and Ref. C5 of the IDS filed August 22, 2006 and considered November 10, 2006. Accordingly, claims directed to zinc finger proteins that can be binding to non-accessible regions do not render the claimed complexes obvious.

Since the Office has not demonstrated that complexes as claimed are necessarily formed in any of the cited documents (including the two patents with composition claims), the obviousness-type double patenting rejections cannot be sustained.

35 U.S.C. § 112, 1st paragraph, new matter

The previously-pending claims were rejected under 35 U.S.C. § 112, 1st paragraph as allegedly failing to comply with the written description requirement by containing subject matter that was not described in the originally-filed specification. (Office Action, pages 18-19). In particular, it was alleged that the recitation "non-naturally occurring" represented new matter added after the filing of the application. *Id.*

It is well settled that the proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding

information that goes beyond the subject matter originally filed. See, *e.g., In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981) and MPEP § 2163.06. The Office Action implies that literal support is required, when, in fact, M.P.E.P. § 2163.02 specifically indicates the reverse, namely:

> The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.

Thus, the written description requirement is satisfied if the specification reasonably conveys possession of the invention to one skilled in the art. *See, e.g., In re Lukach,* 169 USPQ 795, 796 (CCPA 1971). The disclosure must be read in light of the knowledge possessed by the skilled artisan at the time of filing, for example as established by reference to patents and publications available to the public prior to the filing date of the application. *See, e.g., In re Lange,* 209 USPQ 288 (CCPA 1981). Moreover, the burden is on the Examiner to provide evidence as to why a skilled artisan would not have recognized that the applicant was in possession of claimed invention at the time of filing. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991); *In re Wertheim,* 191 USPQ 90 (CCPA 1976).

In sum, it is axiomatic that literal description is not required and that a specification need not describe, and preferably omits, that which is known to those working in the field. See, e.g., *Loom Co. v. Higgins*, 105 U.S. 580, 585-86 (1882); *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988) and *In re Gay*, 309 F.2d 769, 774 (CCPA 1962) pointing out that "not every last detail [of an invention need] be described [in a specification], else patent specifications would turn into production specification, which they were never intended to be."

In the instant case, the as-filed specification clearly conveys that Applicants were in possession of non-naturally occurring zinc finger protein as claimed and, moreover, that such non-naturally occurring (e.g., engineered, designed or selected) zinc finger proteins were known to those of skill in the art at the time of filing (page 1, line 21 to page 2, line 21; page 5, lines 14-25; page 17, lines 4-20, emphasis added):

Recently, it has become possible to obtain regulatory proteins which bind to predetermined DNA target sites. Such proteins can be obtained, for example, by using a specific DNA sequence for **selection** of a binding protein from a pool of proteins having fully or partially randomized sequence at certain amino acid residues; or through **design** of a protein having an amino acid sequence known to bind a particular target site, using design concepts that relate the amino acid sequence of the protein to the DNA sequence of the target site. This technology is most highly developed for the class of DNA-binding proteins known as zinc finger proteins (ZFPs). *See*, for example, U.S. Patents 5,789,538; 6,007,988; 6,013,453; WO 95/19431; WO 98/54311; PCT/US00/00388; U.S. Patent Application Serial No. 09/444,241 filed November 19, 1999; U.S. Patent Application Serial No. 09/535,088, filed March 23, 2000; Rebar *et al.* (1994) *Science* **263:**671-673; Jamieson *et al.*(1994) *Biochemistry* **33:**5689-5695; Choo *et al.* (1994) *Proc. Natl. Acad. Sci USA* **91:**11163-11167; and Greisman *et al.* (1997) *Science* **275:**657-661.

Recombinant ZFPs, **selected or designed** by the methods described above, are reported to have the ability to regulate expression of transiently expressed reporter genes and randomly integrated exogenous target genes in cultured cells. For example, a ZFP DNA-binding domain can be fused to a transcriptional activation domain (such as, for example, VP16 or VP64) or a transcriptional repression domain (such as, for example, KRAB, ERD, or SID) to obtain activation or repression, respectively, of a gene adjacent to a target sequence for the ZFP DNA-binding domain. *See*, for example, Choo *et al.* (1994) *Nature* **372:**642-645; Pomerantz *et al.* (1995) *Science* **267:**93-96; Liu *et al.* (1997) *Proc. Natl. Acad. Sci. USA* **94:**5525-5530; and Beerli *et al.* (1998) *Proc. Natl. Acad. Sci. USA* **95:**14628-14633.

Kang *et al.* (2000) *J. Biol. Chem.* **275:**8742-8748 report the effects of cellular expression of **engineered** ZFPs on the transcription of extrachromosomal and integrated reporter genes. They reported that an **engineered** ZFP was able to override transcriptional activation of a reporter gene by a GAL4-VP16 fusion protein. These authors did not disclose a method for selecting a binding site for an exogenous molecule in cellular chromatin.

Beerli *et al.* (2000) *Proc. Natl. Acad. Sci. USA* **97:**1495-1500 report regulation of endogenous *erbB2* and *erbB3* genes with **designed** ZFPs. However, they do not disclose methods for selecting a binding site for an exogenous molecule in cellular chromatin.

In another embodiment, an accessible region is identified within a region of interest and a ZFP target site is located within the accessible region. A ZFP that binds to the target site is designed. The **designed** ZFP can be introduced into the cell, or a nucleic acid encoding the designed

ZFP can be **designed** and the **designed** nucleic acid can be introduced into the cell, where it will express the **designed** ZFP. Methods for the **design and/or selection** of ZFPs that bind specific sequences are disclosed in U.S. Patent No. 5,789,538; U.S. Patent No. 6007,408; U.S. Patent No. 6,013,453; PCT WO 95/19431; PCT WO 98/54311 co-owned PCT/US00/00388 and references cited therein; co-owned U.S. Patent Application Serial No. 09/444,241, filed November 19, 1999; and co-owned U.S. Patent Application Serial No. 09/535,088, filed March 23, 2000. Methods for selection include, but are not limited to, phage display and *in vivo* selection.

In a preferred embodiment, an exogenous molecule is a zinc finger DNA-binding protein (ZFP). Certain ZFPs, their properties and their binding sequences are known in the art, as described *supra*. Furthermore, it is possible, for any particular nucleotide sequence, to **design and/or select** one or more ZFPs capable of binding to that sequence and to characterize the affinity and specificity of binding. *See*, for example, U.S. Patent No. 5,789,538; U.S. Patent No. 6007,408; U.S. Patent No. 6,013,453; PCT WO 95/19431; PCT WO 98/54311 co-owned PCT/US00/00388 and references cited therein; co-owned U.S. Patent Application Serial No. 09/444,241, filed November 19, 1999; and co-owned U.S. Patent Application Serial No. 09/535,088, filed March 23, 2000. Certain sequences, such as those that are G-rich, are preferred as ZFP binding sites. Since a three-finger ZFP generally binds to a 9- or 10-nucleotide target site, in a preferred embodiment, an accessible region, present within a region of interest in cellular chromatin, is searched for one or more G-rich sequences of 9-10 nucleotides and, for each sequence so detected, a ZFP can be designed to bind those sequences. In addition, two three finger modules can be joined, *via* an appropriate linker domain, to form a six-finger protein capable of recognizing an 18-20 nucleotide target site. *See*, for example, PCT/US99/04441.

Furthermore, as the skilled artisan was aware at the time of filing, the terms "designed," "engineered," and "selected" were all used to refer to non-naturally occurring zinc finger proteins. See, e.g., Refs. AH-1, AI-1, AL-1, AM-1, AN-1, AQ-1, AR-1, AT-1, AW-1, of the IDS mailed on May 3, 2002 and considered July 19, 2004.

Thus, the skilled artisan would have no doubt that the as-filed specification, in light of the state of the art at the time of filing, describes providing a complex comprising a non-naturally occurring zinc finger protein as the term "non-naturally occurring" is

implicit in the disclosure that the zinc finger protein is engineered (*e.g.,* designed and/or selected) to bind to a target site in an accessible region of cellular chromatin.

Applicants also note that the Board of Patent Appeals and Interferences has recently reaffirmed that the term "naturally occurring" would be understood by the persons of skill in the art to mean that it exists or is found in nature. *See,* page 3 of *Ex parte Dewis et al.* (2007) Appeal 2007-1610 (BPAI), attached hereto. Plainly, the skilled artisan would know that "non-naturally occurring" refers to zinc finger proteins that do not exist or are found in nature.

Since it is clear that the skilled artisan would have known that Applicants were in possession of complexes comprising non-naturally occurring zinc finger proteins as claimed, namely by engineering via design or selection a zinc finger protein that does not occur in nature, withdrawal of the rejection is in order.

35 U.S.C. §§ 102

A. MacKay

Previous claims 57, 63, 64, 68, 70 and 87-90 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by MacKay et al. (1998) *J. Biol. Chem.* 273:30560-67. (Office Action, pages 19-20). MacKay was cited for teaching introduction of nucleic acid encoding mutant GATA-1 proteins into NIH3T3 cells which proteins bound to plasmid that was alleged to "necessarily" have a chromatin structure. *Id.*

The pending claims have been amended to incorporate the limitations of claim 66, which is not subject to the rejection. Indeed, as acknowledged by the Examiner, MacKay does not disclose cells in which GATA-1 is bound to cellular chromatin. See, also, page 10, lines 7-10 of the specification for a definition of cellular chromatin. Because a plasmid is not chromosomal cellular chromatin as claimed, MacKay cannot anticipate the pending claims.

B. Schwechheimer

Previous claims 57, 63, 64, 66, 69 and 87-90 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schwechheimer et al. (1998) *Plant Molecular Biology*

36:195-204 (hereinafter "Schwechheimer"). (Office Action, pages 20-21). Schwechheimer was cited for disclosing a GAL4-VP16 fusion protein bound to a plasmid reporter construct. *Id.*

As with MacKay, Schwechheimer fails to in any way describe a complex between a non-naturally occurring zinc finger protein and chromosomal cellular chromatin. Rather, the GAL4-VP16 fusion of this reference is bound to plasmid DNA, which does not have the structure of cellular chromatin. Furthermore, the GAL4 domain of the fusion protein is a naturally occurring protein. The pending claims require that the zinc finger protein of the complex be non-naturally occurring. Thus, the rejection based on Schwechheimer should be withdrawn.

C. Knoke

Previous claims 57, 63, 64, 66, 68, 71 and 87-90 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Knoke et al. (1999) *Human Genetics* 104:257-261, which was cited for teaching HeLa cells co-transfected with plasmids encoding androgen receptors and reporter plasmids. (Office Action, page 21).

As with Schwechheimer, reporter plasmids are not chromosomal cellular chromatin as set forth in the claimed complexes and androgen receptors are not non-naturally occurring zinc finger proteins. Therefore, the rejection cannot be sustained.

D. Oliveira

Previous claims 57, 66, 70 and 87-90 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Oliveira et al. (1998) *Chromosome Research* 6:205-211, which was cited for teaching fluorescence *in situ* hybridization of heterochromatin (FISH) in cells. (Office Action, page 22).

The pending claims are drawn to complexes comprising a zinc finger protein bound to an accessible region in cellular chromatin. The FISH techniques disclosed in Oliveira do not include zinc finger proteins. In addition, FISH techniques involve denaturation of the chromosomal DNA prior to hybridization. Therefore, a complex including cellular chromatin as claimed is not formed in Oliveira. See, e.g., Oliveira,

page 206, left column 8 lines from the bottom, noting that "chromosomal DNA was denatured... ."

Thus, Oliveira does not describe or demonstrate the claimed complexes.

E. Boyes

Claims 57, 63, 64 and 87-90 were again rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Boyes. (Office Action, pages 22-23). The Office Action alleges that fragments of GATA-1 are non-naturally occurring and that the "reconstituted" chromatin is cellular chromatin, as claimed. *Id.*

As noted above with regard to MacKay, claim 66 was not subject to this rejection. The pending claims include the limitations of previous claim 66 and, accordingly, the rejection should be withdrawn.

F. Various co-owned patents

Previous claims 57, 63, 64, 66, 68-71 and 87-90 were rejected over 18 co-owned U.S. Patents, as applied in the obviousness-type double patenting rejection. (Office Action, pages 23-24). In support of this rejection, the Office Action stated (Office Action, page 24, emphasis added):

> As shown in the double patenting rejections above, each of these patents claim embodiments which **make obvious** the various claimed subject matter. Moreover, the specifications each **teach essentially** the same subject matter with regard to the artificial proteins and artificial chemicals which bind to the cellular chromatin in the cell and/or outside the cell.

Applicants traverse the rejection and supporting remarks.

Anticipation is a rigorous standard – every limitation of the claim at issue must appear identically in a single reference for a rejection under 35 U.S.C. § 102 to stand. *In re Bond,* 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Inherent anticipation cannot be established by probabilities or possibilities (see, *Continental Can Co. USA , Inc. v. Monsanto Co.,* 20 USPQ2d 1746, 1749 (Fed. Cir. 1991):

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Thus, in order to show inherent anticipation, the burden is on the Examiner to show that the cited references teach cells in which the engineered zinc finger protein is necessarily and inevitably bound to accessible regions of cellular chromatin.

For the reasons of record, the Examiner has not met this burden. The allegations that the references "make obvious" or "teach essentially" the claimed subject matter are untenable and, in any event, cannot support an anticipation rejection. For the reasons of record, none of the documents anticipate the pending claims.

Indeed, a rejection based on U.S. Patent No. 6,534,261 has previously been made and withdrawn in this case. See, e.g., pages 2-3 of Response filed July 6, 2005. In particular, as previously established with regard to U.S. Patent No. 6,534,261 (and is relevant the other newly cited 17 co-owned patents), these patents do not show that their engineered zinc finger proteins are necessarily binding to an accessible region of cellular chromatin. Rather, as demonstrated in Zhang et al. (Ref. C5 of IDS filed August 22, 2006 and considered November 10, 2006), engineered zinc finger proteins can be functional when bound to non-accessible regions. See, also, Wong et al. (1997) (Exhibit A of Response filed July 6, 2005 and Ref C4 of IDS filed August 22, 2006 and considered November 10, 2006) and Cirillo et al. (1998) (Exhibit B of Response filed July 6, 2005 and Ref C1 of IDS filed August 22, 2006 and considered November 10, 2006), evidencing that naturally occurring transcription factors also do not necessarily bind to accessible regions of cellular chromatin.

For the foregoing reasons, the cited U.S. Patents do not anticipate the pending claims and, therefore, withdrawal of the rejections is in order.

CONCLUSION

For the reasons set forth herein, allowance of the claims under consideration, and rejoinder and allowance of the withdrawn claims, are requested.

Respectfully submitted,

Date: February 26, 2008

By: 

Dahna S. Pasternak
Registration No. 41,411
Attorney for Applicants

ROBINS & PASTERNAK LLP
1731 Embarcadero Road, Suite 230
Palo Alto, CA 94303
Telephone: (650) 493-3400
Facsimile: (650) 493-3440

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARK LAWRENCE DEWIS,
DAVID JOHN EDWARDS, LESLEY KENDRICK,
MARIA WRIGHT, and AMIR YUSUF

Appeal 2007-1610
Application 10/955,833
Technology Center 1600

Decided: September 4, 2007

Before TONI R. SCHEINER, LORA M. GREEN, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 7-12. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF CASE

A problem with developing flavoring agents for fruity and herbaceous materials, such as mango flavor, is that natural plant materials do not contain a single flavoring agent, but rather contain a complex mixture of volatile components making identification of characteristic flavors very difficult.

> The volatiles of mango were analyzed by gas chromatography and a combined gas chromatograph-mass spectrometer. The volatiles were also analyzed by gas chromatography on a sulfur detector.

(Spec. 2: 21-27).

The Specification describes the discovery that ethyl 3-mercaptobutyrate – identified from mango – can be used as a flavoring and perfuming agent because of its unique flavor and odorant properties (Spec. 1-2). The claims are drawn to an ingestible composition comprising an ingestible vehicle and ethyl 3-mercaptobutyrate.

The following rejections are on appeal in this proceeding:

1) Claims 7-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Answer 13);

2) Claims 7-12 stand rejected (three separate rejections: of claims 7-12, 10-12, and 7; Answer 7, 9, and 13, respectively) under 35 U.S.C. § 112, second paragraph, as indefinite;

3) Claims 7-9 stand rejected under 35 U.S.C. § 102 as anticipated by Nielsen ("Stereoselective Reduction of Thiocarbonyl Compounds with Baker's Yeast," *Tetrahedron: Asymmetry*, 5: 403-410, 1994; referred to by the Examiner as "Nielson and Madsen") (Answer 11); and

4) Claim 7 stands rejected under 35 U.S.C. § 102(b) as anticipated by Lazier (US 2,402,639, issued Jun. 25, 1946; referred to by the Examiner as "Lazier and Signaigo") (Answer 12).

The claims in each rejection stand or fall together because separate reasons for patentability were not provided for any individual claim. We select claims 7 and 10 as representative for deciding all rejections in this appeal. *See* 37 C.F.R. § 41.37(c)(1)(vii). Claims 7 and 10 read as follows:

> 7. An ingestible composition comprising:
> (i) an ingestible vehicle; and
> (ii) an organoleptically effective amount of ethyl 3-mercaptobutyrate represented by the formula, $CH_3(SH)CHCH_2COOCH_2CH_3$ provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds.
>
> 10. The ingestible composition according to claim 7, wherein the ingestible composition is a beverage product.

CLAIM INTERPRETATION

Claim 7 is drawn to an ingestible composition comprising (i) an ingestible vehicle and (ii) ethyl 3-mercaptobutyrate "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or a part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds."

At issue in this appeal is the proper interpretation of "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds." We give the words in a claim their broadest reasonable interpretation as they would be understood by persons of skill in the art in the context of the Specification. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). In this case, the phrase "naturally occurring mixture of compounds" does not appear in the Specification as originally filed. However, "naturally occurring" would be understood by persons of skill in the art to mean that it exists or is found in nature – that is, it is "a product of nature" and not "a product of human ingenuity." *Diamond v. Chakrabarty*, 447 US 303, 309, 313 (1980). Thus, we interpret a

"naturally occurring mixture of compounds" to mean a "mixture of compounds" that can be found in nature.

Ethyl 3-mercaptobutyrate was identified by the inventors as a flavorant present in the "complex mixture" of components that naturally occur in mango (Spec. 2: 21-27 and 5: 33 to 6:12). In this context, we interpret "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds" to mean that the mercaptobutyrate compound is not present in the claimed composition in the same complex form in which it would occur in nature.

We have considered, but reject, the Examiner's alternative interpretation (Answer 6-7). As we understand it, the Examiner interprets "naturally occurring mixture of compounds" phrase to mean "a mixture of naturally occurring compounds." In our opinion, the Examiner improperly interpreted "naturally occurring" to describe the compounds present in the mixture, rather than the entire mixture, itself.

The term "ingestible" as recited in claim 7 is also at issue in this proceeding. The Specification states the ethyl 3-mercaptobuyrate is useful for imparting a unique flavor to foodstuffs (Spec. 5: 33-35). It is described as useful "in a wide variety of ingestible vehicles" that include gum, confectionary products, and beverages (Spec. 8: 7-14). The term "ingestible" is also defined in the Specification to mean "all materials and compositions which are used by or which perform a function in the body" (Spec. 6: 17-21). Thus, we interpret the phrases "ingestible composition" and "ingestible vehicle" as recited in claim 7 to mean materials and compositions suitable as foods.

Written description rejection

Claims 7-12 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner contends that the phrase "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same as the naturally occurring mixture" of compounds is "new matter" to the application because it is not supported in the Specification as originally filed (Answer 13). "[N]owhere in the written description is language reflecting the present form of claim 7 found" (Final Office Action 9).

"The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required 'to recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.'" *Amgen Inc. v. Hoechst Marion Roussel Inc.*, 314 F.3d 1313, 1330 [65 USPQ2d 1385] (Fed. Cir. 2003) (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561 [19 USPQ2d 1111] (Fed. Cir. 1991)). While there is no requirement that the claimed invention be described in the identical wording that was used in the Specification, there must be sufficient disclosure to show one of skill in this art that the inventor "invented what is claimed." *See Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1235 (Fed. Cir. 2000).

According to the Specification, Appellants discovered that ethyl 3-mercaptobutyrate "possesses unexpected flavor properties and imparts a unique note to flavors" especially in foodstuffs (Spec. 5: 33-37). It is present among "[a] relatively large number of components . . . identified in

an analysis of [a solvent extract of] mango" (Spec. 5: 37 to 38). Ethyl 3-mercaptobutyrate is stated to be "present at such low concentrations in mango that it cannot be isolated from the fruit in a commercially viable way" (Spec. 6: 10-12). Instead, Appellants describe the chemical synthesis of ethyl 3-mercaptobuyrate in a "purified form, unaccompanied by substances of natural origin present in mango" (Spec. 4: 35 to 5: 2) and shows that it acts as a beneficial flavorant (Spec. 38-39 (Example 2)). Thus, Appellants' invention is the discovery that purified ethyl 3-mercaptobutyrate acts as a flavoring when introduced into foodstuffs.

The written description must be of sufficient detail to show possession of the full scope of the invention. *Pandrol USA LP v. Airboss Railway Products Inc.*, 424 F.3d 1161, 1165, 76 USPQ2d 1524, 1527 (Fed. Cir. 2005). In this case, naturally occurring mixtures are excluded from the claims, but that leaves the claim open to everything else that contains ethyl 3-mercaptobutyrate – including any composition, however modified that it is no longer naturally occurring.[1] In our opinion, such a claim scope is not justified nor drawn to what Appellants invented. The invention described in the Specification is "purified" ethyl 3-mercaptobutyrate "unaccompanied by substances of natural origin present in mango" (Spec. 4: 35 to 5: 2) as a novel flavoring or perfuming agent. This is the only invention described in the Specification. There is no detail in the Specification that shows that Appellants possessed compositions of a different scope, let alone of an intermediate scope to cover mixtures of less complexity than the naturally-

[1] Such compositions would include, for example, less complex compositions derived from naturally-occurring mixtures by fractionation, extraction, and other processing steps.

occurring mixture from which ethyl 3-mercaptobutyrate was originally identified.

Granted, the purified ethyl 3-mercaptobutyrate described in the application is "not a part of a naturally occurring mixture of compounds." However, what Appellants invented is a "purified" compound that, when introduced into a foodstuff, imparts a unique flavor to it. The only disclosure with respect to naturally occurring mixtures is that the concentration of ethyl 3-mercaptobutyrate is too low for it to be isolated from mango (Spec. 6: 10-12). As a consequence, ethyl 3-mercaptobutyrate was chemically synthesized – the form which is characterized in the Specification as "purified." In sum, we agree with the Examiner that claim 7 lacks a written description in the application.

Our decision is consistent with *In re Johnson and Farnham*, 558 F.2d 1008, 194 USPQ 187 (CCPA 1977), a CCPA case which dealt with exclusionary language in a claim that was not present in the application upon which priority was based. In *Johnson*, the applicant was attempting to narrow the scope of a claimed genus of compounds by excluding two species which had been lost in an interference. The Examiner, in a rejection affirmed by the Board of Appeals, asserted that the claims were not entitled to the 1963 filing date of the application because the claimed subject matter was not described in it as required by 35 U.S.C. § 112, first paragraph. The CCPA reversed. "The only inquiry is whether, after exclusion from the original claims of two species specifically disclosed in the 1963 application, the 1963 disclosure satisfies § 112, first paragraph, for the 'limited' genus now claimed." *Johnson*, 558 F.2d at 1017-1018, 194 USPQ at 195.

The CCPA found that it did because its priority application contained "a broad and complete generic disclosure, coupled with extensive examples fully supportive of the limited genus now claimed." *Johnson*, 558 F.2d at 1018, 194 USPQ at 196.

The CCPA distinguished an earlier case, Welstead, in which an applicant sought to exclude subject matter from an originally claimed genus, because in that case the new subgenus was not described in the application nor was there a description of "[its] species thereof amounting in the aggregate to the same thing." *Johnson*, 558 F.2d at 1018, 194 USPQ at 196.

The CCPA concluded:

> The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute.

Johnson, 558 F.2d at 1019, 194 USPQ at 196.

In this case, there is no description in the Specification – as there was in *Johnson* – of a genus minus what has been excluded from the claim. The Specification describes only one species – purified ethyl 3-mercaptobutyrate – and no other. There is no detailed description to show that Appellants possessed the invention which is now claimed.

Appellants argue that "[i]t has always been clear that appellant merely wishes to claim ethyl 3-mercaptobutyrate in purified form as an organoleptic agent and not ethyl 3-mercaptobutyrate in a naturally occurring mixture of compounds or part of a synthetic mixture of compounds which is the same

as the naturally occurring mixture of compounds" (Br. 11). However, purified claim ethyl 3-mercaptobutyrate is not what is presently claimed.

Thus, we conclude that the phrase "provided that the ethyl 3-mercaptobutyrate is not part of a naturally occurring mixture of compounds or a part of a synthetic mixture of compounds which is the same as the naturally occurring mixture of compounds" is new matter to the Specification in violation of the written description requirement of 35 U.S.C. § 112, first paragraph. The rejection of claims 7-12 is affirmed.

Indefiniteness rejection under § 112, second paragraph

There are three rejections at issue in this appeal for lack of definiteness under 35 U.S.C. § 112, second paragraph. First, claims 7-12 stand rejected as indefinite because "it is unclear exactly what constitutes, in the context of the invention, 'a naturally occurring mixture of compounds.'" (Answer 7.) Related to this issue, the Examiner states that if the claims are interpreted to exclude any mixture of naturally occurring compounds, "the compositions specified in claims 10-12 lack antecedent basis" because they would exclude Appellants' "most preferred embodiments: the beverage, confection and chewing gum" (Answer 9-10). Third, the Examiner states that claim 7 is indefinite "[b]ecause a naturally occurring mixture and a synthetic mixture are *not* the same, they cannot as a matter of fact properly be characterized as such" (Answer 13).

We reverse the rejections. The phrase "naturally occurring mixture of compounds," when properly interpreted, means a "mixture of compounds" that can be found in nature (see *supra* at p. 3-4). This is not indefinite nor does it lead claims 10-12 to lack antecedent basis.

The characterization of the synthetic mixture as being the "same" as the naturally occurring mixture would be understood by persons of skill in the art to mean that the profile of compounds in the mixtures are the same. Thus, we do not find that this term introduced ambiguity into the claim.

Anticipation by Nielsen

Claims 7-9 stand rejected under 35 U.S.C. § 102 as anticipated by Nielsen.

Nielsen describes the synthesis of ethyl 3-mercaptobutyrate (Nielsen, at 408; Answer 11). The ethyl 3-mercaptobutyrate accumulates in a hexane phase in the reaction vessel (Nielson, at 408; Answer 11). The Examiner contends that "[s]ince hexane is an ingestible vehicle, in the broadest reasonable interpretation of the term, when considered in light of the instant specification, the Nielsen . . . reference is anticipatory. Hexane is capable of being ingested, thus it is an ingestible material" (Answer 11).

Appellants contend that hexane is not an "ingestible vehicle" as would be understood in the light of the Specification (Br. 7-8). "As set out in appellant's specification, 'ingestible' means to take in as food. Appellant's specification states that '[a]pplicant has discovered that ethyl 3-mercaptobutyrate . . . possesses unexpected flavor properties and imparts a unique note to flavors, *especially for conferring in foodstuffs* . . .' Appellant's specification at page 5, lines 27-31. (emphasis added)" (Br. 8). Appellants provide evidence that hexane is "a toxic substance causing central nervous system effects including dizziness, giddiness, nausea, and headache" and therefore not ingestible as a food (Br. 7-8).

In our opinion, Appellants have the better argument. Claim terms are given their broadest reasonable interpretation as they would be understood by persons of ordinary skill in the art when read in the context of the Specification. We have interpreted "ingestible" to mean a material that can be present in a food (see *supra* at p. 4) because the Specification describes the invention as purified ethyl 3-mercaptobutyrate as a flavoring to be used in foodstuffs (Spec. 5: 33-38). The Examiner's interpretation of "ingestible vehicle" is broad, but not *reasonable* in light of the Specification's teaching about the use of ethyl 3-mercaptobutyrate in food.

Appellants have introduced evidence, unrebutted by the Examiner, that hexane is a toxic substance and therefore would not be considered an "ingestible vehicle" as required by claim 7. We find this evidence persuasive, and thus concur with Appellants that the Examiner erred in rejecting claims 7-9 as anticipated by Nielsen. We reverse this rejection.

Anticipation by Lazier

Claim 7 stands rejected under 35 U.S.C. § 102(b) as anticipated by Lazier.

Lazier teaches the synthesis of ethyl 3-mercaptobutyrate having 87% purity (Lazier, at col. 3, ll. 35-37; Answer 12). The Examiner contends that this composition meets the limitation of claim 7 requiring the presence of an ingestible vehicle "because there is some additional material contained besides the mercapto-ester compound (the 'ingestible vehicle')" (Answer 12).

Appellants contend that "[t]he Examiner may NOT assume that this additional material (13%) is an ingestible material. Lazier et al. does not

identify this additional material. This additional material could just as readily be one or more toxic (non-food) substances. Lazier et al. was not seeking to make flavoring agents for use in ingestible vehicles but rather was seeking to make starting materials for use in polymers (Lazier et al. at col. 1, lines 4-9). Hence, Lazier et al. was not concerned whether this additional material (13%) was an ingestible material" (Br. 10).

"A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003) (internal citations omitted). *See* also *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F3d 1331, 1343 74 USPQ2d 1398, 1406 (Fed. Cir. 2005). "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The issue raised by this rejection is whether the Examiner has provided a reasonable basis for shifting the burden to Appellants to establish that the claimed composition is distinguishable from Lazier's composition; and if so, whether Appellants' burden has been met. In our opinion, the Examiner met his burden, but Appellants did not.

Lazier's Example II, relied upon by the Examiner for its disclosure of a fraction that "analyzes for 87% purity as ethyl 3-mercaptobutyrate" (Lazier, at col. 3, ll. 36-38), also comprises "[w]ater . . . formed in the course

of the reaction" (Lazier, at col. 3, ll. 38-39). Since water is an ingestible vehicle, we conclude that its presence is enough to provide reasonable basis for considering Lazier's composition to be the same as the composition of claim 7. Appellants had the opportunity to provide evidence that Lazier's synthetic method would not result in an ingestible composition as required by claim 7, but no evidence was offered in rebuttal. Accordingly, we affirm the rejection.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Ssc

RICHARD R. MUCCINO
758 SPRINGFIELD AVENUE
SUMMIT, NJ 07901